

REMARKS

This paper is in response to the Office action mailed March 9, 2007, and to the Notice of Non-Compliant Amendment mailed October 5, 2007. A petition for one-month extension of time, with an authorization to charge Deposit Account No. 13-2855 in the amount of \$120.00, was submitted on July 9, 2007. In the event any additional fees are due, kindly charge the cost thereof to our Deposit Account No. 13-2855.

Applicants' Interview Summary

The Examiner's courtesy extended at the personal interview¹ of May 31, 2007 is appreciated. The Applicants' undersigned representative reviewed and agrees with the Interview Summery prepared by the Examiner and agrees with its contents. In compliance with 37 CFR 1.133(b) and in response to the Notice of Non-Compliant Amendment, the Applicants provide the following summary of the interview, which is believed to be in accord with the Examiner's interview summary:

During the interview, Applicants' undersigned representative discussed the office action of March 9, 2007 and claim 1 in view of the references Maurer, U.S. Patent No. 6,200,939 and Ahmad et al., U.S. Patent No. 5,885,591. The Examiner explained how Maurer and Ahmad read on pending claims. Applicants' undersigned representative discussed that in order for the polyhydric alcohol to be used as a lubricant, the polyhydric alcohol is required to have a high molecular weight. Maurer teaches a polyhydric alcohol as a decrystallizer (col. 4, lines 59-64). The Examiner indicated glycerin, which Maurer teaches as a polyhydric alcohol, is typically used in the art as a lubricant and/or surfactant. Applicants' undersigned representative indicated

¹ The Applicants' representative notes that the box on the Interview Summary is checked to indicate the interview was telephonic, but this should be corrected to reflect that the interview was in person.

in order for glycerin to be used as a decrystallizer as taught by Maurer, it would require a low molecular weight and would be contrary to its use as a lubricant. The Examiner suggested an amendment positively reciting a crucial molecular weight or a showing by persuasive arguments and/or affidavit that the polyhydric alcohol in Maurer could not be used as a lubricant.

Agreement was not reached.

Rejections under 35 U.S.C. § 102

Claims 1, 7, 8 and 9 were rejected under 35 U.S.C. § 102 as allegedly anticipated by Maurer, U.S. Patent No. 6,200,939. Claim 1 recites:

A lubricating deodorant for ostomy pouches comprising an aqueous solution containing both a water-soluble lubricating agent capable of wetting and clinging to interior wall surfaces of polymeric film materials of the pouch and a compatible water-soluble complexing agent capable of complexing with and neutralizing the odor-causing molecules of fecal matter.

It is respectfully submitted that Maurer does not anticipate the Applicants' claim 1, because Maurer does not disclose or suggest a lubricating agent, as recited in claim 1. As discussed in column 4, lines 58-63 of Maurer, the biocompatible cleaning and deodorizing compositions include a polyhydric alcohol in an amount effective to assist in dissolving crystal materials, such as uric acid crystals. In a preferred embodiment, glycerin is used as the polyhydric alcohol. The Maurer reference discloses the use of glycerin and other polyhydric alcohols not as a lubricating agent, but rather, to assist in dissolving crystals. Neither in the cited passages, nor anywhere else in the reference, does Maurer make any mention of a lubricant, a lubricating deodorant, or a lubricating agent.

The Office action's reliance on Maurer as teaching a lubricating deodorant that comprises an aqueous solution containing both a water-soluble lubricating agent capable of wetting and clinging to interior wall surfaces of polymeric film materials of the pouch and a compatible

water-soluble complexing agent capable of complexing with and neutralizing odor-causing molecules in fecal matter is believed to be based on the Maurer reference's disclosure of glycerin as a polyhydric alcohol, and an unstated assumption that Maurer's disclosure of glycerin is understood by those in the art to be tantamount to a disclosure of a lubricating agent.

By definition, a lubricant is "a substance used to reduce friction between parts or objects in relative motion" (McGraw-Hill Dictionary of Scientific and Technical Terms (2002)) (*see also* Webster's Third New International Dictionary (2002), defining lubricant as "a substance capable of reducing friction, heat, and wear when introduced as a film between solid surfaces").

Therefore, in order to act as a lubricating agent, a solution containing glycerin in the concentrations disclosed in Maurer should have the effect of reducing the dynamic coefficient of friction between two films. On July 9, 2007, the Applicants submitted by U.S. mail a Declaration of Bettakeri Udayakumar Under 37 C.F.R. §1.132, attesting to the results of comparative average dynamic coefficient of friction (COF) testing between two films representing the walls of an ostomy pouch, showing that a solution containing glycerin in the concentrations disclosed in Maurer produces no such reduction in the dynamic COF.

As shown in the test results presented with the Declaration, an additive of 3% Glycerin had essentially the same measured average dynamic COF, 0.363, as that of 100% water, which measured 0.356. The measured average dynamic COF of 0.363 for the additive of 3% Glycerin was also essentially the same as having no additive between the pouch film sheets, which had an average measured dynamic COF of 0.355. A 3% Propylene Glycol additive also had essentially the same average measured dynamic COF of 0.365. By contrast, when employing a solution falling within the scope of the Applicants' claims, and which is marketed under the trademark "Adapt®," testing under identical conditions resulted in a significantly reduced measured

average dynamic COF of 0.050, roughly an order of magnitude difference. The differences between the measured dynamic COF of the Adapt® solution and that of 100% water, an additive of 3% Glycerin, and an additive of 3% Polypropylene Glycol, as well as a blank pouch (with no additive) are illustrated graphically in the test results submitted with the Declaration. Based on these test results, that demonstrate the friction between two ostomy pouch film sheets is actually *increased* when employing an additive of 3% Glycerin (as compared to no additives between pouch film sheets, as well as compared to an additive of water alone between the pouch film sheets), Maurer does not teach a lubricating deodorant that comprises an aqueous solution containing both a water-soluble lubricating agent capable of wetting and clinging to interior wall surfaces of polymeric film materials of the pouch and a compatible water-soluble complexing agent capable of complexing with and neutralizing odor-causing molecules in fecal matter.

In addition, the Applicants submit that *esters* of polyhydric alcohols, e.g. esters of glycerol, may be considered lubricants. *See, e.g.*, Bock, U.S. Patent No. 4,684,473. However, prior use of esters of polyhydric alcohols as lubricants does not transform Maurer's teaching of polyhydric alcohol as a decrystallizing agent into a teaching of a lubricating agent.

Withdrawal of the rejection under 35 U.S.C. § 102(b) of claims 1 and 7-9 is respectfully solicited.

Rejections under 35 U.S.C. § 103

Claims 2 and 3 were rejected as allegedly being unpatentable over Maurer, U.S. Patent No. 6,200,939. The Office action concedes that Maurer does not disclose a complexing agent that is a surfactant. However, the Office action indicates it would have been obvious to one having ordinary skill in the art to incorporate the complexing agent and surfactant into one substance. Even assuming that it would have been obvious to modify Maurer by incorporating the complexing agent and surfactant into one substance, such a modification of Maurer would still not result in the Applicants' claims 2 and 3. Claims 2 and 3 recite, directly or by reference to independent claim 1, the "lubricating agent." As discussed above with respect to claim 1, and as demonstrated in the test results attached to the Declaration of Bettakeri Udayakumar Under 37 C.F.R. §1.132 submitted by mail on July 9, 2007, Maurer fails to disclose or suggest the use of a lubricating agent with a compatible water-soluble complexing agent capable of complexing with and neutralizing the odor-causing molecules of fecal matter. Withdrawal of the rejection of claims 2 and 3 is respectfully solicited.

Claims 4 and 5 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Maurer in view of Ahmad et al., U.S. Patent No. 5,885,591. While the Office action (as best understood²) concedes Maurer does not disclose a cellulose lubricating agent, the Office action

² The Office action, at page 3, states "However, Maurer does not discloses [sic.] a polyhydric alcohol lubricating agent instead of a cellulose lubricating agent." It is understood this was intended to read 'Maurer discloses a polyhydric alcohol lubricating agent instead of a cellulose lubricating agent.' However, if this indeed is what was intended, the Applicants respectfully disagree with this statement, inasmuch as Maurer does not disclose a lubricating agent. See discussion of claim 1, above. As emphasized in the language added to claim 1 in the Amendment dated December 4, 2006, the claimed lubricating agent must be "capable of wetting and clinging to interior wall surfaces of polymeric film materials," such as those typically used as the walls of an ostomy pouch, and by definition, must reduce the friction between the film materials.

concludes that “one of ordinary skill in the art would have found it obvious to substitute polyhydric alcohol for a cellulose lubricant.” The Applicants respectfully disagree with the characterization of Ahmad et al. as disclosing “both materials [i.e., polyhydric alcohol and cellulose lubricating agent] [] comprise lubricating compositions.” The cited passage of Ahmad et al., column 2, lines 1-31, merely recites the presence of polyhydric alcohol and cellulose gum in a personal lubricant composition. However, there is no disclosure that the polyhydric alcohol may be used interchangeably with cellulose gum, and thus there is no evidence that one of ordinary skill in the art would consider the polyhydric alcohol and cellulose gum to be equivalents, as suggested by the examiner. To the extent the Office action relies upon polyhydric alcohol and cellulose gum as being “art-recognized equivalents,” documented evidence of such equivalency is respectfully solicited.

The cited passage of Ahmad et al. explicitly states that increasing the level of cellulose gum results in *decreasing* lubricity of the compositions of the invention, and that “[t]here is an optimum concentration of cellulose gum that imparts lubricity.” Had the reference intended to disclose polyhydric alcohol as contributing toward lubricity, the reference would have likely expressly stated that polyhydric alcohol was being used as a lubricant, or at least included language similar to the discussion of the optimal concentration of cellulose gum. However, Ahmad et al. has no such discussion of polyhydric alcohol as a lubricant. Notably, consistent with the Applicants’ findings shown in the test results submitted with the accompanying Declaration, the cited passage of Ahmad et al. even points out that “increasing the cellulose gum concentration … thereby decreases the lubricity.” Col. 2, lines 30-31.

The mere substitution of a polyhydric alcohol for a cellulose gum would not result in what is recited in Claims 4 and 5. Because Maurer lacks any teaching of a lubricant, there is no

(Substitute) Response and Applicants' Interview Summary, dated October 15, 2007

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suggestion or motivation to make a substitution of a cellulose gum, such as

hydroxyethylcellulose, hydroxypropylcellulose, or hydroxypropylmethylcellulose, for the polyhydric alcohol disclosed in Maurer. Furthermore, inasmuch as both Maurer and Ahmad et al. lack any suggestion of combining in an aqueous solution both a water-soluble lubricating agent and a compatible water-soluble complexing agent capable of complexing with and neutralizing the odor-causing molecules of fecal matter, it is respectfully submitted that a prima facie case of obviousness of claims 4 and 5 has not been established. Withdrawal of the rejection of claims 4 and 5 is respectfully requested.

Allowed Claims

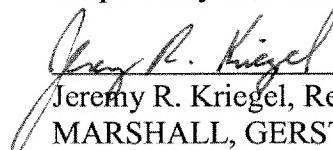
The Applicants note, with appreciation, the allowance of claims 10-14.

Conclusion

In view of the foregoing, it is respectfully submitted that all pending claims of the present application are in condition for allowance. The Examiner's reconsideration and favorable action are respectfully requested. If the Examiner has any questions that might easily be resolved by telephone, the Examiner is invited to contact the Applicants' undersigned representative at (312) 474-6300.

Date: October 15, 2007

Respectfully submitted,



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